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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/535,951	03/27/2000	Alan D. Schreiber	555-56	4293

7590

08/27/2002

Nixon & Vanderhye PC
1100 North Glebe Rd 8th Floor
Arlington, VA 22201-4714

EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/535,951

Applicant(s)

SCHREIBER, ALAN D.

Examiner

San-ming Hui

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 8-13.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ADVISORY ACTION

Continuation of 2):

The proposed amendment is not sufficient to overcome the rejections under 35 USC 112, second paragraph. It is still not clear what effect(s) is encompassed by the claims. Is it a positive effect or a negative effect? Please note that the effect of medroxyprogesterone on the function of the sex organ is dose-dependent. For example, a 20mg of medroxyprogesterone would produce a stronger effect on the function of sex organ than a 5mg of medroxyprogesterone. The instant claim does not recite the dose of medroxyprogesterone and therefore, fail to make clear what effect of medroxyprogesterone is being compared with the instant progestational agent.

Continuation of 5):

Applicant's rebuttal arguments averring the cited prior art fail to teach that neovascularization causes atherosclerotic plaque and therefore, no motivation is provided by the cited prior art to administer 17-hydroxyprogesterone to reduce atherosclerotic plaque, have been considered but are not found persuasive. Kuzuya et al. clearly provides a motivation to inhibit angiogenesis (neovascularization) in order to reduce the atherosclerotic lesion (plaque) (See particularly 658, col. 1, second paragraph).

Applicant's rebuttal arguments averring Cincotta et al. and de Gruiter et al. not teaching or suggesting the instant invention via the newly discovered mechanism have been considered, but are not found persuasive. de Gruijter et al. teaches

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Hypercholesterolemia or combined Hypercholesterolemia-hypertriglyceridemia could increase the adhesion of monocytes to the endothelium of the vessel wall that result in atherosclerotic plaque (See abstract). Therefore, by lowering the serum triglyceride and cholesterol level, one of ordinary skill in the art would reasonably expect the atherosclerotic plaque load to be reduced. Since haloperidol is a known prolactin enhancer, which is known to be useful in reducing triglycerides and cholesterol level, employing haloperidol, a prolactin enhancer, to lower serum triglyceride level and reduce atherosclerotic plaque thereby would be reasonably expected to be useful, absent evidence to the contrary.

Since the proposed amendments filed July 29, 2002 would not be entered, the rejections set forth in the final office action mailed March 28, 2002 will remain. No new unanswered rebuttal argument is seen herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
August 26, 2002